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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
David I. FREED) Group Art Unit: 3739
Application No.: 10/760,520) Examiner: Kasztejna, M.
Filed: January 21, 2004) Confirmation No.: 1095
For: ENDOSCOPIC DEVICE HAVING)
SPRAY MECHANISM AND)
RELATED METHODS OF USE)

Mail Stop Appeal Brief-Patents

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REPLY BRIEF UNDER BOARD RULE § 41.41

In reply to the Examiner's Answer mailed June 23, 2008, the period for response to which extends to August 23, 2008, and further to Board Rule § 41.41, Appellant presents this Reply Brief. If any fees are required, Appellant requests that the fees be charged to Deposit Account No. 06-0916.

Arguments

The following remarks address points raised in the “Response to Argument” section (10) of the Examiner’s Answer. Appellant’s lack of response to any particular assertion in the Examiner’s Answer is not a concession of that point.

A. The References Do Not Disclose an “End Effector Consisting Essentially of a Snare Loop”

The Examiner’s “Response to Argument” first addresses features recited in independent claims 1, 34, 47, and 59 of an “end effector consisting essentially of a snare loop.” Dependent claims 101 and 102 recite similar features.

The Examiner states “absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, ‘consisting essentially of’ will be construed as equivalent to ‘comprising’ (see M.P.E.P. 211[1].03).” Examiner’s Answer, page 10. M.P.E.P. 2111.03 further states, however, that “[i]f an applicant contends that additional steps or materials in the prior art are excluded by the recitation of ‘consisting essentially of,’ applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant’s invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964).” Not only does the specification support that the basic and novel characteristics of the claimed invention include a single device that combines a spraying mechanism with an end effector only used for cutting, but also the introduction of additional components to the end effector would materially change those characteristics.

The specification consistently describes a spraying mechanism integrated with an end effector that *only* cuts and does not perform other functions, such as capturing

and retrieving. For example, paragraph [001] of the specification describes the field of the invention as relating to “an endoscopic device that combines tissue cutting and spraying in a single device.” (Emphasis added). Paragraph [005], in the first sentence of the “Summary of the Invention,” describes a device that “combin[es] the ability to perform polypectomy and dye spraying in a single device.” Polypectomy is the cutting of a polyp from, for example, the colon. The specific embodiments detailed and shown in the “Description of the Embodiments” section of the specification have an end effector that only cuts. The Figures show only snare loops 40, 340, 440, which only cut, as the end effectors. For example, paragraph [024] of the specification and Figures 1-6 detail an endoscopic device 10 having “an end effector, such as snare loop 40, and a nozzle member 50 attached to a distal tip 49 (as shown in Fig. 5) of the snare loop 40.” Paragraphs [040] and [041] describe a suitable, exemplary procedure as polypectomy, “severing the tissue received in the snare loop 40.” See also paragraph [047] describing retraction of “snare loop 340 to sever the tissue received.” The specification therefore clearly emphasizes that the basic and novel characteristics of the claimed invention include a single device that combines a spraying mechanism with an end effector only used for cutting.

Certain additional benefits derive from combining such an end effector with a spraying mechanism. For example, as shown in Figures 2 and 6, the snare loop 40 is relatively small and takes up relatively little space within the lumen of the tubular member 20 of the device 10. Since the end effector of the device is only a snare loop, and does not include additional structure such as wires for capturing and retrieving, the device uses only one control member 25 to actuate the snare loop. This control

member 25 also occupies relatively little space within the lumen. As a result, even when the snare loop and the control member are disposed in the lumen, there is little inhibition of fluid flow through the lumen to the nozzle 50. A basic and beneficial characteristic of the claimed invention, therefore, is a snare loop that simply cuts tissue and does not significantly inhibit spraying of fluid when disposed in the device. The introduction of additional components other than a snare loop into an end effector would materially change these characteristics.

On page 11 of the Examiner's Answer, the Examiner asserts that Levinson discloses "a [second] set of wires 28 that is a snare loop and functions as a tissue cutting end effector," yet concedes that Levinson also discloses a "first set of wires 20 . . . used for capturing and retrieving the cut tissue." Thus, to the extent that Levinson shows an "end effector," the "end effector" includes two sets of wires, one for cutting and a second for capturing and retrieving the cut tissue. The combination of Konomura and Levinson therefore results in an "end effector" with additional components as compared to the claimed "end effector consisting essentially of a snare loop." These additional components materially change the characteristics of the claimed invention, since the additional components also capture and retrieve tissue and, to a greater extent, inhibit spraying of fluid when disposed in the device.

For these reasons, the combination of Konomura and Levinson does not disclose or suggest an end effector consisting essentially of a snare loop, as recited in independent claims 1, 34, 47, and 59, and dependent claims 101 and 102.

B. The References Do Not Disclose an “End Effector [that] Consists of” a Snare Loop

The Examiner’s Answer briefly mentions, but fails to separately and fully address, features recited in dependent claims 97-100. Each of these dependent claims recites an “end effector [that] consists of” a snare loop.

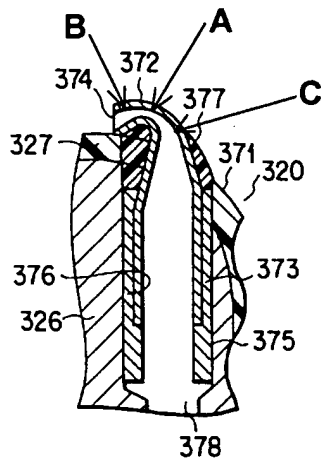
As set forth in M.P.E.P. § 2111.03, “[t]he transitional phrase consisting of excludes any element, step or ingredient not specified in the claim.” Citing *In re Gray*, 53 F.2d 520 (CCPA 1931) (emphasis added). See also *Mannesmann Demag Corp. v. Engineered Metal Products Co.*, 793 F.2d 1279, 1282 (Fed. Cir 1986) (“The district court correctly observed that the phrase consisting of appears in clause (a), not the preamble of the claim, and thus limits only the element set forth in clause (a). The court correctly declined to read this usage of consisting of as excluding all other elements from the claim as a whole.”).

The Examiner’s “Response to Argument” discusses the claims that recite “consists of” along with claims that recite “consisting essentially of” and provides no separate analysis or reasons. It is well settled, however, that “consists of” is never interpreted as “comprising,” but rather requires the exclusion of any additional element not specified in the claims. See M.P.E.P. § 2111.03. As discussed above, page 11 of the Examiner’s Answer admits that “Levinson teaches a [second] set of wires 28 that is a snare loop and functions as a tissue cutting end effector” and a “first set of wires 20 . . . used for capturing and retrieving the cut tissue.” Thus, the Levinson “end effector” includes a set of wires that is a snare loop and a set of wires used for capturing and retrieving the cut tissue. Because the combination of Konomura and Levinson includes

an “end effector” with more than a “snare loop,” the combination does not include an “end effector [that] consists of” a snare loop, as recited in dependent claims 97-100. For these reasons, the combination of Konomura and Levinson does not disclose or suggest the features recited in dependent claims 97-100.

C. The References Do Not Disclose that a “Portion of a Flow Path has a Cross-Sectional Area Smaller than Both a Cross-Sectional Flow Area of an Inlet of the Flow Path and a Cross-Sectional Flow Area of an Outlet of the Flow Path”

The Examiner’s Answer addresses features recited in independent claim 69 of a “portion of a flow path ha[ving] a cross-sectional area smaller than both a cross-sectional flow area of an inlet of the flow path and a cross-sectional flow area of an outlet of the flow path.” Dependent claims 89 and 93 recite similar features.



F I G. 30B

The Examiner’s Answer states, on page 12, “[i]t can clearly be seen in Fig 30b [of Okada], that a portion of nozzle 372 has a smaller cross-sectional **area** of both an inlet and outlet cross-sectional **areas**.” (Emphasis added). Appellant disagrees. Figure 30B of Okada is reproduced at left, with added notations “A,” “B,” and “C.” As discussed in the Appeal Brief, Okada does not describe any cross-sectional areas of washing nozzle 372. Further, the figures of Okada, including Figure 30B, do not expressly provide

information about the relationship between the cross-sectional **areas** of an inlet, an outlet, and a portion therebetween of washing nozzle 372. Although the figures show that within washing nozzle 372, at least a portion of a flow path has one **dimension** that

is smaller than a **dimension** of an inlet and a **dimension** of an outlet, the figures do not show whether a portion of the flow path within washing nozzle 372 has a cross-sectional **area** smaller than both a cross-sectional **area** of an inlet and a cross-sectional **area** of an outlet of washing nozzle 372. More specifically, annotated Figure 30B of Okada shows only that a **dimension** at location "A" is smaller than a **dimension** at location "B" and a **dimension** at location "C." Contrary to the Examiner's assertions, however, Figure 30B does not disclose any cross-sectional **areas**, at locations "A," "B," "C," or otherwise.

Moreover, it is not inherent that washing nozzle 372 of Okada includes a portion that "has a cross-sectional area smaller than both a cross-sectional flow area of an inlet of the flow path and a cross-sectional flow area of an outlet of the flow path." It is possible that the flow path of washing nozzle 372 at location "A," for example, actually has a larger cross-sectional area than either or both of locations "B" and "C." Without knowing other dimensions of the flow path within washing nozzle 372, which are neither shown nor described in Okada, it is not "necessarily" the case that the portion having one smaller dimension also has a smaller cross-sectional area.

For these reasons, the combination of Konomura, Levinson, and Okada does not disclose or suggest the claimed features recited in independent claim 69 and dependent claims 89 and 93.

D. The References Do Not Disclose that a "Flow Path Comprises an Inlet and a Plurality of Outlets Connecting to the Inlet"

The Examiner's Answer addresses features recited in independent claim 87 of a "flow path [that] comprises an inlet and a plurality of outlets connecting to the inlet." The

Examiner reiterates the assertion that “Termanini teaches of an analogous surgical instrument having head 36 with apertures 40 to permit injection of a solution into the body during operation (See Figs. 1-2 and 6-7).” Examiner’s Answer, page 12. As discussed in the Appeal Brief, however, because there is still “no apparent reason to combine” the teachings of the applied references, it would not have been obvious to combine Termanini with Konomura and Levinson.

The Supreme Court reviewed the requirements of a proper obviousness analysis in applying 35 U.S.C. § 103(a) in *KSR Int’l Co. v. TeleFlex Inc.*, 127 S. Ct. 1727 (2007). In that decision, the Supreme Court reiterated that it was “important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *Id.* at p. 1741. The Court stated that “it will be necessary . . . to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit.” *Id.* (Emphasis added).

Termanini discloses a fiber-optic catheter 12 for visual inspection of the cardiovascular system. See column 2, lines 49-52. Catheter 12 includes a spray head 36 for dispersing liquid into the bloodstream to displace the blood with the clear saline for improved viewing. See column 4, lines 25-50. In contrast, the purpose of the fluid passage in distal tip 7 of Konomura is to permit a continuous supply of fluid when the end of sheath 2 is closed with distal tip 7. See column 4, lines 14-35, of Konomura. Nothing in Konomura suggests the need for “greater accuracy and efficiency when delivering fluids, such as contrast agents, during an assortment of different surgical procedures,” as alleged on page 12 of the Examiner’s Answer. So, even if the alleged

teaching of Termanini were available to one skilled in the art, he or she would not have modified the fluid passages of Konomura to employ spray head 36 of Termanini.

Moreover, modifying distal tip 7 of Konomura to have a plurality of apertures, as allegedly taught by Termanini, would complicate the design of distal tip 7 of Konomura and unnecessarily require increased fluid pressure for injection of fluid across distal tip 7 of Konomura. Such adverse effects would have sufficiently deterred one of ordinary skill in the art from modifying distal tip 7 of Konomura to employ spray head 36 of Termanini.

The Examiner's Answer reiterates the assertion that "[v]arying the nozzle configuration in the device of Konomura and Levinson would aid in the removal of foreign matter from a target site within the body, as providing alternate nozzle configurations (such as those taught by . . . Termanini) would allow for greater accuracy and efficiency when delivering fluids, such as contrast agents, during an assortment of different surgical procedures." Examiner's Answer, page 12. In the Appeal Brief, Appellant indicated that the Examiner provided no support or factual basis for these allegations. The Examiner's Answer still does not provide any basis for these assertions.

For these reasons, the combination of Konomura, Levinson, and Termanini does not disclose or suggest the claimed features recited in independent claim 87.

Conclusion

For the reasons given above, and the reasons in Appellant's Appeal Brief filed April 2, 2008, the allowance of rejected claims 1-7, 10-18, 28-37, 39, 40, 43-53, 56, 58-64, 66, 67, 69-75, 81, 82, 87-89, 93, and 97-102 is requested.


Further, withdrawn claims 19-21, 23-27, 41, 42, 57, 68, 76-80, 83-86, 90-92, and 94-96 depend from the above-discussed allowed claims, and are therefore allowable for at least the same reasons. Consideration on the merits, and the allowance, of these withdrawn claims is requested.

If there are any fees due in this matter, please charge the fees to Deposit Account 06-0916.

Respectfully submitted,

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Dated: August 6, 2008

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